

# Effect of lowering the transition metals and ammonium concentration in human culture media on the quality of the human embryos.

No registrations found.

|                              |                |
|------------------------------|----------------|
| <b>Ethical review</b>        | Not applicable |
| <b>Status</b>                | Pending        |
| <b>Health condition type</b> | -              |
| <b>Study type</b>            | Interventional |

## Summary

### ID

NL-OMON29264

### Source

NTR

### Brief title

Tramm-ex

### Health condition

In vitro fertilisation, human embryo, embryo culture, ammonium, transition metals

## Sponsors and support

**Primary sponsor:** GIFT, ZOL, Genk, Belgium Private infertility center in a university-affiliated teaching hospital and Newcastle Fertility Centre at LIFE, Newcastle, UK, University affiliated Center.

M. Nijs, GIFT, Genk and Herbert M, LIFE, Newcastle.

**Source(s) of monetary or material Support:** Tramm-ex will be provided by Birr Biosciences

## Intervention

## Outcome measures

### Primary outcome

Embryo quality (quality and cell number in embryo) and clinical pregnancy rate.

### Secondary outcome

1. Metabolomic profiling of embryo culture medium;
2. delivery rate;
3. health of baby.

## Study description

### Background summary

The presence of ammonium in human embryo culture medium has a negative effect on embryo physiology and biochemistry. Ammonium concentration will increase due to spontaneous degradation of amino acids as well as by the metabolism of the embryo. Traces of transition metals like copper or iron can have a detrimental effect on embryo development as well. Removal of these embryo-toxic elements during embryo culture could improve the health and quality of the human embryo.

Tramm-ex is a zeolite block with cross linked gelatin and is an inorganic ion exchanger. Laboratory test have shown that Tramm-ex removes 50% of the ammonium content as well as a factor 100.000 of the transition metals from culture medium. Zeolite has no negative effect on mouse embryo development. The sperm survival test did not identify the Tramm-ex blocks as embryotoxic. In this prospective randomised study, human embryos will be cultured with and without Tramm-ex. Embryo quality and health as well as clinical pregnancy rates will be evaluated.

### Study objective

Removal of transition metals and ammonium from human IVF culture system by an inorganic ion exchanger in the form of a zeolite block packed in gelatine will improve the health and quality of cultured human embryos.

### Study design

Embryo quality (during the 5-day embryo culture) and clinical pregnancy rate (12 days and 6 weeks after embryo transfer).

## Intervention

Embryo culture will be performed with or without the inorganic ionexchanger Tramm-ex. The randomisation is performed by 'the research randomizer' on 100 consecutive patients undergoing IVF/ICSI treatment in each centre. Each centre receives a list for randomisation. Randomisation is performed at the time of check for fertilisation. Embryo scoring and selection for transfer and/or cryopreservation is done according to standard methods. Single embryo transfer from either culture system is done on day 3, 4 or 5.

## Contacts

### Public

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### Scientific

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## Eligibility criteria

### Inclusion criteria

Patients entering the IVF/ICSI program.

### Exclusion criteria

1. ICSI cases for preimplantation genetic diagnosis;
2. ICSI cases with testicular spermatozoa.

## Study design

## Design

|                     |                             |
|---------------------|-----------------------------|
| Study type:         | Interventional              |
| Intervention model: | Parallel                    |
| Allocation:         | Randomized controlled trial |
| Masking:            | Open (masking not used)     |
| Control:            | Active                      |

## Recruitment

|                           |             |
|---------------------------|-------------|
| NL                        |             |
| Recruitment status:       | Pending     |
| Start date (anticipated): | 01-02-2009  |
| Enrollment:               | 100         |
| Type:                     | Anticipated |

## Ethics review

|                   |                |
|-------------------|----------------|
| Not applicable    |                |
| Application type: | Not applicable |

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

| Register | ID      |
|----------|---------|
| NTR-new  | NL1511  |
| NTR-old  | NTR1581 |

**Register**

Other  
ISRCTN

**ID**

intern : GIFTNFC2009-1  
ISRCTN wordt niet meer aangevraagd

## Study results

**Summary results**

N/A